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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/25/2001

Roberto Fagnani

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3521

7590

10/14/2005

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,728	Applicant(s) FAGNANI ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 31-42 is/are pending in the application.
- 4a) Of the above claim(s) 8,12-14,36 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11,15-18,31-35,37,41 and 42 is/are rejected.
- 7) ☒ Claim(s) 18 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20051005</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>See Office Action</u> . | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

Application and Claims Status

1. Applicant's amendment and response filed 07/26/2005 is acknowledged and entered. Claims 19-30 have been cancelled. Claim 7 has been amended. Claims 31-42 have been added.
2. The preliminary amendment filed 10/25/2004: amended the specification to add SEQ ID NO for the sequences.
3. A substitute specification was filed on 12/19/2003, which include Abstract and Claims.
4. Claims 1-18, and 31-42 are pending.

Election/Restrictions

5. Applicant's election with traverse of Group I (Claims 1-17) in the reply filed on 07/26/2005 is acknowledged.

The traversal is on the ground that Group II (Claim 18) should be rejoin with Group I because the structural feature of both Group I and Group II are not distinct for '*both groups define biochips having hydrogel cells to which binding entities, such as proteins, are attached which function in exactly the same manner*'. Thus, Group I and Group II should be rejoined.

This is found persuasive and Group I and Group II are rejoined. Therefore, Group I is Claims 1-18 and the new claims 31-42.

Additionally, applicant stated that '*Applicants do not traverse the restriction entered between the claims of Group I and claims 19-30, and these claims have been cancelled, with consideration being presently given to their submission in a divisional application.*' Thus, the restriction requirements among Group I (Claims 1-18, and 31-42), Group III (Claims 19 and 20), Group IV (Claims 21-23), Group V (Claims 24-28), and Group VI (Claims 29 and 30) are still deemed proper and are therefore made FINAL.

6. Claims 19-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *nonelected inventions*, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 07/26/2005. Additionally, claims 19-30 are cancelled by the amendment filed 07/26/2005.

7. Applicant has elected the following species for the elected invention (Claims 1-18, and 31-42) in the reply filed on 07/26/2005:

a. A single specific species of hydrogel cell. Applicant elected '*a hydrogel formed from an isocyanate-functional polymer, more specifically a polymer with urethane linkages, still more specifically a urethane polymer which comprises polyethylene glycol, and yet more specifically one which is the product of a reaction with a polyisocyanate, such as toluene diisocyanate (see page 12, line 33).*' This election is interpreted as a polyethylene glycol that is end-capped with toluene diisocyanate.

b. A single specific species of binding entity. Applicant elected '*that the binding entity is a protein, and more particularly an immunoglobulin (see page 14, line 11).*'

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- c. A single specific species of intermediate agent. *Note: this species was required for the invention of Group II (Claim 18).* Applicant elected telephonically nitrilotriacetic acid found on page 19 line 31 and example 12 (see interview summary). *Note: In the substitute specification, the elected species is found on page 20, line 17.*
8. Claims 8, 12-14, 36, and 38-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *nonelected species*, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/26/2005 and phone interview of 10/5/2005.
9. Claims 1-7, 9-11, 13-18, 31-35, 37, 41, and 42 are under consideration in this Office Action.

Priority

10. This instant application claimed the benefit to a provisional application of 60/243, 699 filed 10/26/2000. This instant application is granted the benefit of priority for 60/243,699 under 35 U.S.C 119(e). Additionally, this instant application is a CIP of PCT/US00/11282 filed 04/26/2000, which is a CIP of 09/299,831 filed 04/26/1999.

However, the instant claims 3 and 4 are granted the benefit of priority for PCT/US00/11282 under 35 U.S.C 120, and the instant claims 1, 2, 5, 6, 8 (withdrawn), 15, and 17 are granted the benefit of priority for 09/299,831 under 35 U.S.C 120. Therefore, the effective filing date for claims 1, 2, 5, 6, 8 (withdrawn), 15, and 17 is 04/26/1999, and the

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effective filing date for claims 3 and 4 is 04/26/2000. The effective filing date for claims 7, 9-14, 18, and 31-42 is 10/26/2000.

Information Disclosure Statement

11. The information disclosure statements (IDS) filed on 06/06/2002, 10/07/2002, and 06/09/2005 have been reviewed, and its references have been considered as noted on PTO-1449 forms.

Claim Objections

12. Claims 18 and 41 are objected to because of the following informalities: Both claims recite the phrase “*hydrogel of said cells*” in lines 5-6 of claim 18 and lines 6-7 of claim 41 and it is unclear if this phrase refers to the term ‘*hydrogel cells*’ of line 2 in both claims or an additional structural limitation. Appropriate correction is required.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-3, 6, 7, 9, 31, 32, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartdegen et al. (US Patent 4,098,645).

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Hartdegen et al. disclose the compositions comprising polymers with immobilized or bound protein (see e.g. Abstract; col. 1, lines 12-28; col. 3, lines 12-34). The protein includes immunoglobulin, enzymes, and antibodies (refers to instant claimed binding entity/protein binding entities and instant claims 9 and 35)(see e.g. col. 3, lines 14-15; col. 6, lines 56-63). The polymers comprise of isocyanate-capped polyurethane prepolymer that is prepared from toluene diisocyanate and polyethylene glycol (refers to instant claimed hydrogel cells; instant claimed isocyanate-functional polymer/urethane linkages; and instant claims 2, 3, and 32)(see e.g. col. 3, lines 44 thru col. 4, line 11; col. 6, lines 1-16). The protein is bound to the isocyanate group of the polymer and the amount of isocyanate group in the polymer ranges from 10-25% (refers to instant claims 6, 7, and 34)(see e.g. col. 7, line 61 thru col. 8, line 3; col. 8, line 54 thru col. 9, line 8). The composition is pack into a column (refers to instant claimed solid substrate)(see e.g. col. 13, lines 64-67; col. 16, lines 1-41). Therefore, the composition of Hartdegen et al. anticipates the presently claimed biochip.

15. Claims 1-3, 9, 10, 15, 17, 18, 31, 32, 37, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Sundberg et al. (US Patent 5,624,711).

Sundberg et al. disclose derivatized supports with an array of ligands (see e.g. Abstract; col. 1, lines 6-14 and 64-67; col. 2, lines 15-37). The derivatized supports comprise a polymer-coated support (refers to instant claimed solid substrate and hydrogel cells) and an array of ligands such as peptides (refers to instant claimed binding entity/protein binding entities and instant claim 9)(see e.g. col. 5, lines 25-35; col. 5, line 66 thru col. 6, line 10; col. 6, lines 18-35; col. 13, lines 46-52). The support comprises a surface with predefined regions such as wells (see

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e.g. col. 5, line 66 thru col. 6, line 10; col. 6, lines 18-35; col. 11, lines 20-27), and a diverse array of ligands is produced on the substrate (refers to instant claims 15 and 37, and instant claimed 'd)' limitation of claims 18 and 41) (see e.g. col. 6, lines 56-59; col. 9, lines 43-53). The polymer coating includes polyurethanes or polyethylene glycol and isocyanate functional group for the attachment of the ligands (refers to instant claimed isocyanate-functional polymer/urethane linkages, and instant claims 2, 3, 10, 17, and 32)(see e.g. col. 5, lines 25-35; col. 11, lines 59-62; col. 12, lines 38-41). Therefore, the supports of Sundberg et al. anticipate the presently claimed biochip.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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18. Claims 1-7, 9, 10, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US Patent 6,406,921) and Hartdegen et al. (US Patent 4,098,645).

Wagner et al. disclose an array of proteins comprising a plurality of patches in discrete, known regions on a substrate, where the protein has different, known sequence is immobilized on each patch and the method of making an array of protein capture agents (see e.g. Abstract; col. 3, lines 26-29; col. 3, lines 44-47; col. 3, lines 56-58; col. 6, lines 45-52; col. 7, lines 17-19; col. 8, lines 10-17). The array comprises of a monolayer (refers to instant claimed hydrogel) on the surface of the substrate and the proteins are immobilized on the monolayer (see e.g. col. 8, lines 10-17; col. 11, lines 15-28 and 39-53). The monolayer comprises the formula of X-R-Y wherein X is the functional group that binds to the surface of the substrate, R is a hydrocarbon chain with the hetero groups such as $-(OCH_2CH_2)_n-$ with $n=1-20$, and Y is the functional group that binds to the protein such as isocyanate (see e.g. col. 8, lines 10-17; col. 10, lines 10-26; col. 11, lines 15-28 and 39-53). Moreover regarding the claimed thickness of the hydrogel (claims 4 and 5), the thickness of the hydrogel would be a choice of experimental design and is considered within the purview of the cited prior art since Wagner et al. disclose that the monolayer can be of any thickness on the substrate (see e.g. col. 5, lines 15-26). Additionally, the protein can be attached to the Y functional group via an affinity tag (refers to instant claimed intermediate agent)(see e.g. col. 11, lines 15-28; col. 12, line 59 thru col. 13, line 12). The type of protein includes enzyme and antibodies (see e.g. col. 7, lines 34-47). The substrate comprise patterned such as walls (see e.g. col. 9, lines 55-64).

The array of Wagner et al. differs from the presently claimed invention by failing to disclose a polymer comprising an isocyanate-capped polyurethane prepolymer.

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Hartdegen et al. disclose the compositions comprising polymers with immobilized or bound protein (see e.g. Abstract; col. 1, lines 12-28; col. 3, lines 12-34). The protein includes immunoglobulin, enzymes, and antibodies (refers to instant claimed binding entity/protein binding entities and instant claims 9 and 35)(see e.g. col. 3, lines 14-15; col. 6, lines 56-63). The polymers comprise of isocyanate-capped polyurethane prepolymer that is prepared from toluene diisocyanate and polyethylene glycol (refers to instant claimed hydrogel cells; instant claimed isocyanate-functional polymer/urethane linkages; and instant claims 2, 3, and 32)(see e.g. col. 3, lines 44 thru col. 4, line 11; col. 6, lines 1-16). The protein is bound to the isocyanate group of the polymer and the amount of isocyanate group in the polymer ranges from 10-25% (refers to instant claims 6, 7, and 34)(see e.g. col. 7, line 61 thru col. 8, line 3; col. 8, line 54 thru col. 9, line 8). The composition is pack into a column (refers to instant claimed solid substrate)(see e.g. col. 13, lines 64-67; col. 16, lines 1-41).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a polymer comprising an isocyanate-capped polyurethane prepolymer as taught by Hartdegen et al. in the array of Wagner et al. One of ordinary skill in the art would have been motivated to disclose a polymer comprising an isocyanate-capped polyurethane prepolymer in the array of Wagner et al. for the advantage of providing bound proteins with long service life (Hartdegen: col. 14, lines 13-40) since both Wagner et al. and Hartdegen et al. disclose binding protein via the isocyanate functional group (Wagner: col. 11, lines 39-53; Hartdegen: col. 7, line 61 thru col. 8, line 3). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Wagner et al. and Hartdegen et al. because Hartdegen et al. shown the success of binding proteins to the

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isocyanate-capped polyurethane prepolymer via the examples (Hartdegen: col. 16, lines 1-61).

Therefore, the combine teachings of Wagner et al. and Hartdegen et al. do render the biochip of the instant claims *prima facie* obvious.

19. Claims 31-35, 37, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundberg et al. (US Patent 5,624,711) and Hartdegen et al. (US Patent 4,098,645).

Sundberg et al. disclose derivatized supports with an array of ligands (see e.g. Abstract; col. 1, lines 6-14 and 64-67; col. 2, lines 15-37). The derivatized supports comprise a polymer-coated support (refers to instant claimed solid substrate and hydrogel cells) and an array of ligands such as peptides (refers to instant claimed binding entity/protein binding entities)(see e.g. col. 5, lines 25-35; col. 5, line 66 thru col. 6, line 10; col. 6, lines 18-35; col. 13, lines 46-52). The support comprises a surface with predefined regions such as wells (see e.g. col. 5, line 66 thru col. 6, line 10; col. 6, lines 18-35; col. 11, lines 20-27), and a diverse array of ligands is produced on the substrate (see e.g. col. 6, lines 56-59; col. 9, lines 43-53). The polymer coating includes polyurethanes or polyethylene glycol and isocyanate functional group for the attachment of the ligands (refers to instant claimed isocyanate-functional polymer/urethane linkages)(see e.g. col. 5, lines 25-35; col. 11, lines 59-62; col. 12, lines 38-41).

The array of Sundberg et al. differs from the presently claimed invention by failing to disclose a polymer comprising an isocyanate-capped polyurethane prepolymer.

Hartdegen et al. disclose the compositions comprising polymers with immobilized or bound protein (see e.g. Abstract; col. 1, lines 12-28; col. 3, lines 12-34). The protein includes immunoglobulin, enzymes, and antibodies (refers to refers to instant claimed binding

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entity/protein binding entities and instant claims 9 and 35)(see e.g. col. 3, lines 14-15; col. 6, lines 56-63). The polymers comprise of isocyanate-capped polyurethane prepolymer that is prepared from toluene diisocyanate and polyethylene glycol (refers to instant claimed hydrogel cells; instant claimed isocyanate-functional polymer/urethane linkages; and instant claims 2, 3, and 32)(see e.g. col. 3, lines 44 thru col. 4, line 11; col. 6, lines 1-16). The protein is bound to the isocyanate group of the polymer and the amount of isocyanate group in the polymer ranges from 10-25% (refers to instant claims 6, 7, and 34)(see e.g. col. 7, line 61 thru col. 8, line 3; col. 8, line 54 thru col. 9, line 8). The composition is pack into a column (refers to instant claimed solid substrate)(see e.g. col. 13, lines 64-67; col. 16, lines 1-41).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a polymer comprising an isocyanate-capped polyurethane prepolymer as taught by Hartdegen et al. in the array of Sundberg et al. One of ordinary skill in the art would have been motivated to disclose a polymer comprising an isocyanate-capped polyurethane prepolymer in the array of Sundberg et al. for the advantage of providing bound proteins with long service life (Hartdegen: col. 14, lines 13-40) since both Sundberg et al. and Hartdegen et al. disclose binding protein via the isocyanate functional group (Sundberg: col. 5, lines 25-35; Hartdegen: col. 7, line 61 thru col. 8, line 3). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Sundberg et al. and Hartdegen et al. because Hartdegen et al. shown the success of binding proteins to the isocyanate-capped polyurethane prepolymer via the examples (Hartdegen: col. 16, lines 1-61). Therefore, the combine teachings of Sundberg et al. and Hartdegen et al. do render the biochip of the instant claims *prima facie* obvious.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1-3 and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 8, 12, 16, and 26 of U.S. Patent No. 6,174,683 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed device of claim 1 of the instant application, i.e. a biochip, and the method of making a device of claim 1 of the U.S. Patent No. 6,174,683, i.e. the method of preparing a biochip, have overlapping scope since the device of claim 1 of the instant application is generic to the resulting device of the method of U.S. Patent No. 6,174,683, or in other words, claims 1-3 and 6 are anticipated by claims 1, 2, 6, and 8 of U.S. Patent No. 6,174,683. Specifically, both devices have similar structural features that are a solid substrate, polyurethane-based hydrogel comprising isocyanate-capped polyethylene oxide, and biomolecule wherein the biomolecule is bound to the polyurethane-based hydrogel, which is bound to the solid support. Therefore, the resulting device of the method of U.S. Patent No. 6,174,683 is *prima facie* obvious over the instant claimed device.

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22. Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-41 of U.S. Patent No. 6,174,683. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed device of claim 1 of the instant application, i.e. a biochip, and the device of claim 1 of the U.S. Patent No. 6,174,683, i.e. the polyurethane-based hydrogel biochip, have overlapping scope since the device of claim 1 of the instant application is generic to the device of U.S. Patent No. 6,174,683, or in other words, claims 1-7 are anticipated by claims 36-41 of U.S. Patent No. 6,174,683. Specifically, both devices have similar structural features that are a solid substrate, polyurethane-based hydrogel comprising isocyanate-capped polyethylene oxide, and biomolecule wherein the biomolecule is bound to the polyurethane-based hydrogel, which is bound to the solid support. Therefore, the device of U.S. Patent No. 6,174,683 is *prima facie* obvious over the instant claimed device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
October 12, 2005


PADMASHRI PONNALURI
PRIMARY EXAMINER